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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,329

Applicant(s)

BURBANK ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10-28,35-39 and 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9,29-34 and 40-46 is/are rejected.
- 7) ☐ Claim(s) 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4,5,6,10/04;8/05;6/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Species III, in the reply filed on 16 October 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicant elected Species III, claims 34-36, for examination. However, "a tissue grasping assembly comprising an arm" (claims 35-36) reads on Species V (Figure 8). In addition to claim 34, claims 1-4, 7-9, 29-33, and 40-46 read on Species III (Figure 3). Therefore, claims 1-4, 7-9, 29-34, and 40-46 have been examined.

Claims 5-6, 10-28, 35-39, and 47-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 October 2006. The requirement is made FINAL.

Specification

3. The disclosure is objected to because of the following informalities: in paragraph 35, drive member is defined as element 33. Replace "33" with --34-- on page 12, lines 2 and 3. In paragraph 36 remove the extra period (".") from the last line. In paragraph 38, elements 18 and 23 are defined as "handles" when they have been previously defined as a first elongated member and a proximal portion. Appropriate correction is required.

Claim Objections

4. Claim 46 is objected to because of the following informalities: unnecessary brackets ("[]"). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 40 recites the limitation "the atraumatic distal tip." There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 40, 42-44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohajer (Patent No. 5,464,409). Mohajer discloses an intravaginal device (see Figures 1, 4, and 7) comprising an elongated resilient (column 4, line 1), or "malleable", guide rail (30) with an end (32) "configured to" receive and guide a medical instrument (whether or not it is attached to a slidable coupling element since the distal end is "free" or open), and a tissue grasping mechanism (tenaculum 56) secured to the distal portion of the guide rail (30) having two elongated members (not labeled) pivotally

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connected at a pivot point (not labeled) on the same side of the guide rail (30) having finger grips (not labeled) and a sharp point (the elongated member tapers from a large diameter to a narrow point). Mohajer further discloses a "collar" (shield member 12) mounted on the guide rail (30) that moves in a longitudinal direction (column 2, lines 57-60).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer in view of Molinelli (Patent No. 1,571,956).

Mohajer discloses a device as described above, however, does not disclose the distal section of the guide rail is made of a soft metal. Molinelli discloses an obstetrical instrument made of thin soft metal, preferably silver (page 1, lines 94-96), in order for it to easily bend and shape itself during use (page 1, lines 15-21). It would have been

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obvious to one of ordinary skill in the art at the time the invention was made to construct the distal section of the guide rail of Mohajer from silver as taught by Molinelli in order to allow the device to conform to the anatomy of the patient, in turn preventing injury (page 1, lines 9-14).

11. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer. Mohajer discloses a device as described above, however, does not disclose the specific length and diameter of the guide rail or the length of the distal tip. It is well known in the art that female anatomical structures vary in size (length and width) from patient to patient. It would have been obvious to one of having ordinary skill in the art at the time the invention was made to construct the guide rail and distal tip with the parameters claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

12. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer in view of Hasson (Patent No. 5,368,598). Mohajer discloses an intravaginal device (see Figures 1, 4, and 7) comprising an elongated guide rail (30) with an end (32) "configured to" receive and guide a medical instrument and a tissue grasping mechanism (tenaculum 56) secured to the distal portion of the guide rail (30) having two elongated members (not labeled) pivotally connected at a pivot point (not labeled) on the same side of the guide rail (30). Mohajer does not disclose a therapeutic or diagnostic medical instrument slidably disposed on the guide rail.

Hasson discloses an intravaginal device (Figure 4) comprising an elongated

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guide rail (142) and a tissue grasping mechanism (tenaculum 124). Hasson further discloses a therapeutic instrument (plastic tube 60) slidably disposed on the guide rail, since the plastic tube (60) surrounds the guide tube (52) and shifting between the plastic tube (60) and the guide rail (52) may occur (column 2, lines 52-57; column 4, lines 43-56). The plastic tube is a therapeutic instrument in the sense that it repositions at least one of an organ or vessel and lowers the risk of damaging adjacent tissue and organs (column 2, lines 39-40 and 24-33). It would have been obvious to one of ordinary skill in the art at the time was made to construct the device of Mohajer with a therapeutic or diagnostic medical instrument slidably disposed on the guide rail as taught by Hasson in order to reduce the risk of damaging surrounding tissue and organs.

13. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer in view of Hasson (Patent No. 5,037,430). Mohajer discloses a device as described above, however, does not disclose a securing element on the tissue-grasping element. Hasson discloses a clamp for gynecological instruments (Figure 2). Hasson teaches a securing element (ratcheted lock tabs 38) on the tissue-grasping element (10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the tissue grasping element of Mohajer with a securing element as taught by Hasson in order to hold the tissue grasping element in the clamped position (column 3, lines 13-15).

14. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohajer in view of Hasson (Patent No. 5,562,680). Mohajer discloses a device as described

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above, however, does not disclose the collar is threaded. Hasson discloses an apparatus (Figure 6) having an elongated guide rail (34; since it is the central portion of the device) with a "collar" (extension 36) that supports the uterus in a desired working orientation (column 4, lines 52-54). Hasson teaches a threaded connection between the collar (36) and guide rail (column 4, lines 54-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a threaded connection between the collar and guide rail of Mohajer as taught by Hasson in order to be able to keep the collar from sliding when in a selected position, while still enabling a way to provide a custom fitting (column 4, lines 55-63).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the threads on an exterior portion of the guide rail (rather than an interior portion) and on the interior of the collar (rather than on the exterior), since the "collar" of Mohajer is disposed over the guide rail, not through it.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9:00 a.m. - 6:30 p.m., alternate Fridays 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
October 25, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/25/06